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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,482	02/02/2001	Richard A. Shimkets	15966-577A CIP3 (Cura-77)	7782
7590	06/28/2002			
Ivor R. Elrifi Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. One Financial Center Boston, MA 02111			EXAMINER ANDRES, JANET L	
			ART UNIT 1646	PAPER NUMBER DATE MAILED: 06/28/2002 9

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/775,482	SHIMKETS ET AL.
	Examiner	Art Unit
	Janet L Andres	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 06 May 2002.
- 2a)  This action is **FINAL**.                                    2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-47 is/are pending in the application.
  - 4a) Of the above claim(s) 27-47 is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-26 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some \*    c)  None of:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a)  The translation of the foreign language provisional application has been received.
- 15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

<ol style="list-style-type: none"> <li>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.</li> </ol>	<ol style="list-style-type: none"> <li>4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____.</li> <li>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</li> <li>6) <input type="checkbox"/> Other: _____</li> </ol>
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## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group I, detection of PDGFD, antigens in Paper No. 8 is acknowledged. The restriction requirement of paper no. 6 is made FINAL. Claims 1-47 are pending in this application. Claims 27-47 are withdrawn from consideration as being drawn to a non-elected invention.

### ***Specification***

2. The specification is objected to because there are sequences on p. 129 that lack sequence identifiers.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(c) the invention was described in—

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or  
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

4. Claims 1-19 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 01/00878 (priority date 30 June, 1999), WO 00/66736 (priority date 3 May 1999), and WO 00/27879 (priority date 10 November, 1998).

WO 01/00878 teaches VEGF G, which is identical to Applicant's SEQ ID NO: 2. See figure 1 and SEQ ID NO: 2. Detection of VEGF G, including detection by antibodies, is taught

in lines 28-30 of p. 6, lines 1-6 of p. 7, lines 21-31 of p. 77, p. 78, and lines 1-15 of p. 79.

Determination of VEGF G levels is taught in lines 13-30 of p. 4 and lines 1-2 of p. 45.

Diagnosis of cancer by detection of VEGF G is taught on p. 11, lines 10-15. Detection of domains is taught on p. 14, line 3.

WO 00/66736 teaches ZVEGF4, which is identical to Applicant's SEQ ID NO: 2. See SEQ ID NO: 2 of the PCT document. Detection, including detection by antibodies and quantitation, is taught in lines 25-28 of p 39. Domains are taught on p. 13. Diagnosis of cancer is taught in lines 28-31 of p. 57.

WO 00/27879 teaches a PDGF D which is identical to Applicant's SEQ ID NO: 2. See figure 8 and SEQ ID NO: 8. Domains are taught on p. 12, lines 19-27. Detection and quantitation by antibodies is taught on p. 19, lines 16-34 of p. 24, and lines 1-2 of p. 25. Quantitation in cancer biopsies is taught in lines 11-13 of p. 20.

The following prior art is also made of record: WO 00/34474 (priority date 7 December, 1998) teaches SEQ ID: 37, which is identical to Applicant's SEQ ID NO: 2.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 20-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex Parte Forman*, (230 USPQ 546 (Bd Pat. App. & Int. 1986)); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

While detection in some cancers is shown, there is no guidance or objective evidence to indicate that levels of PDGF D could be used for staging. No correlation with disease progression is indicated. What is presented are levels in patients with various types of cancer and an outline of art-recognized procedures for determining a correlation with disease state (example 38, p. 147). One of skill in the art would not be able to predict, based on the direction provided in the specification, that PDGF D levels could be used to stage any cancer. Further, the claims are not limited to any particular type of cancer, and it is clear from Applicant's data in Table 15 that levels of PDGF D could not be used to stage or even diagnose all forms of cancer. Thus, without further guidance to indicate in what cancers PDGF D staging could be used, and correlative evidence to indicate how it could be used, it would require undue experimentation for the skilled artisan to use the claimed invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are drawn to methods using "PDGF D", "p35", and "p85". None of these terms are defined in the specification by reference to a particular sequence identifying number or numbers. One of skill in the art would thus not be able to determine what proteins and portions of proteins Applicant intended the invention to encompass. The claims should refer to a sequence presented in the sequence listing. While the name itself may have some notion of the activity of the protein, there is nothing in the claim that distinctly identifies it. Others in the field may isolate the same protein and give it an entirely different name or give the same name to a different protein. Applicant should particularly point out definitive characteristics associated with the protein. Describing biochemical molecules by a particular name fails to distinctly identify what the protein is.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.  
June 24, 2002

*Yvonne Eyler*  
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